

REMARKS

Please reconsider the application in view of the amendments made above and the remarks set out below.

- Claims 1, 2, 4, 5, 8-18, 20-22, and 24-35 are pending.
- Claims 1, 2, 4, 5, 8-18, 21, 22, and 24-35 are rejected.
- Claims 36-44 are newly added.

Claims 1, 5, 22, and 35 have been reformatted. Claims 1, 2, 5, and 22 have been amended to recite "medical device" instead of "stent". Claims 36-40 are newly added and limit claims 1, 2, 5, and 22 to stents. Claims 41-44 are newly added. All of these amendments are fully supported by the application, as filed, and do not present new matter.

35 U.S.C. § 102 Claim Rejections

The examiner has rejected claims 1, 2, and 35 under 35 U.S.C. § 102(e) as being anticipated by Tseng et al., U.S. Patent No. 6,364,903, the 903-patent.

The polymeric coating may be applied to stent 2 using a number of different techniques. Two preferred examples of application of coating 14 include spraying the stent with a spray of PTFE particles or dip coating the stent in a mixture containing PTFE particles. Powder coating generally refers to a variety of methods employing powdered plastics and resins which are used commercially to apply coatings to various articles. These methods include fluidized bed, electrostatic spray, electrostatic fluidized bed, plasma spray, and hot flocking, as well as combinations and variants of these methods.

In the electrostatic spray process, a coating powder is withdrawn from a reservoir in an air stream and electrostatically charged in the high voltage corona field of a spray gun. The charged particles are attracted to the grounded metal object to be coated and adhere to it by electrostatic attraction. The coated substrate is then placed in an oven and the coating is fused to form a substantially continuous film. The discrete PTFE particles form a connected path around the stent. The relatively high viscosity of the PTFE melt serves to effectuate a superior coating. If the powder is

sprayed on a preheated article, the powder melts and fuses directly on the hot surface; further heating to fuse or cure the coating may be required, depending upon the type of coating powder.

903-patent, Column 4 lines 43-67

This excerpt shows that the 903-patent teaches spraying a powder onto a preheated article. On the other hand, when Applicants' claims are read in view of Applicants' disclosure, it is clear that Applicants' claims cover spraying a solvent-containing coating substance onto a heated or temperature-adjusted article. Therefore, the 903-patent does not teach a step of "applying a coating substance" as that phrase is used by Applicants.

The 903-patent also teaches that powder is sprayed onto a preheated article and that this preheated article may require further heating. This does not imply that the article is continuously heated or temperature-adjusted (i.e. that the temperature is "maintained") throughout the deposition process. All this teaches is that the temperature is raised before deposition begins and that it may be raised later. Therefore, the 903-patent does not teach "maintaining the temperature of the device . . . during the applying step". *aL* *...L*

Since the 903-patent does not teach each and every element of claims 1, 2, and 35, it does not anticipate these claims. Please remove this rejection under 35 U.S.C. § 102(e).

35 U.S.C. § 103 Claim Rejections

The examiner has rejected claims 5, 8-14, 22, 26-27, 29, 33, and 34 under 35 U.S.C. § 103(a) as being unpatentable over Fan et al., U.S. Patent No. 5,558,900, the 900-patent.

The examiner alleges that it would have been obvious to one of ordinary skill in the art to use multiple steps to achieve the desired coating thickness. The 900-patent teaches using one step to apply the coating, and the examiner points to the knowledge of one of ordinary skill in the art to supply the aspect of modifying the 900-patent's single-

step process to reach step 5.c). The examiner has failed to cite a secondary reference that is combinable with the 900-patent to teach the utility of substituting a multi-step process, as contained in Applicants' claims, for the 900-patent's single-step process. The Examiner has also failed to provide any *evidence* of motivation to modify the 900-patent's disclosure to provide the claimed limitations.

M.P.E.P. § 2144.03 states that "the rationale for supporting an obviousness rejection may be based on common knowledge in the art or 'well-known' prior art" and the "examiner may take official notice of facts outside of the record which are *capable of instant and unquestionable demonstration* as being 'well-known' in the art." If an applicant traverses such an assertion, the examiner is required to cite a reference in support of her position. Applicants traverse that assertion and ask for such a reference.

In point of fact, the 900-patent expressly rejects substituting a multi-step process for the single-step process it teaches. See below. It teaches away from the modification that the examiner deems obvious.

In comparison to the two-step coating process described by Lambert, the one-step coating process of this invention is not only simpler and less time consuming, but also provides coating of better uniformity and consistency. Moreover, the Faa was lower for the coatings of the present invention and compared to the two step coating of Lambert for both Tecoflex and Polyethylene catheters. This demonstrates a surprising enhancement in the abrasion resistance of the articles of the present invention which comprise a substantially homogeneous composite coating of poly(ethylene)oxide and polyisocyanate. The latter are important characteristics for precision coatings intended for medical applications, such as for coating angioplasty balloons.

The 900-patent, Column 15, line 64-Column 16, line 9.

Finally, even if one of ordinary skill in the art believed that single-step processes were freely substitutable for multi-step processes, Applicants have found otherwise. For instance, the disclosure as filed clearly teaches that single-step application of a liquid to a medical device creates a potential for coating defects. See paragraph 7 of the application, as filed. The examiner's position is that one of ordinary skill in the art believes in the free

substitution of multi-step processes for single-step processes. If that position is correct, then skilled artisans have failed to recognize the problem solved by Applicants – sometimes single-step processes result in inferior coatings. If the prior art did not recognize this problem, it could not have suggested a solution. Please remove this rejection.

Regarding claim 8, claim 8 depends from claim 5 and, therefore, contains all the limitations of claim 5. As discussed above, the 900-patent fails to teach or suggest the elements of claim 5. Thus, the 900-patent also fails to teach or suggest the elements of claim 8. Because claim 8 is patentable regardless of the discussion on page 6 of the office action, second full paragraph. Applicants are not under a duty to discuss that paragraph. Applicants reserve the right to discuss it, if such a duty later arises. Please note that the disclosure as filed describes why spraying is not an obvious substitution for immersion in this invention. See application, paragraph 7, as filed. Please remove this rejection.

Regarding claims 9-10, 12-13, and 29, these claims depend from claim 5 and, therefore, contain all the limitations of claim 5. As discussed above, the 900-patent fails to teach or suggest the elements of claim 5. Thus, the 900-patent also fails to teach or suggest the elements of these claims. Because these claims are patentable regardless of the discussion on page 6 of the office action, third full paragraph. Applicants are not under a duty to discuss that paragraph, but Applicants reserve the right to discuss it if such a duty later arises. Please remove this rejection.

Regarding claim 11, claim 11 depends from claim 5 and, therefore, contains all the limitations of claim 5. As discussed above, the 900-patent fails to teach or suggest the elements of claim 5. Thus, the 900-patent also fails to teach or suggest the elements of claim 11. Because claim 11 is patentable regardless of the discussion on page 6 of the office action, fourth full paragraph. Applicants are not under a duty to discuss that paragraph, but Applicants reserve the right to discuss it if such a duty later arises. Please remove this rejection.

Regarding claim 14, claim 14 depends from claim 5 and, therefore, contains all the limitations of claim 5. As discussed above, the 900-patent fails to teach or suggest the elements of claim 5. Thus, the 900-patent also fails to teach or suggest the elements of claim 14. Because claim 14 is patentable regardless of the discussion on page 7 of the office action, first full paragraph. Applicants are not under a duty to discuss that paragraph, but Applicants reserve the right to discuss it if such a duty later arises. Please remove this rejection.

Regarding claim 22, the 900-patent fails to teach the limitations of claim 22, as outlined above regarding claim 5 and dependent claims.

Regarding claims 27 and 33, these claims depend from claims 5 and 22, respectively, and therefore, they contain all the limitation of claims 5 and 22. As discussed above, the 900-patent fails to teach or suggest the elements of claims 5 or 22. Thus, the 900-patent also fails to teach or suggest the elements of claims 27 and 33. Because claims 27 and 33 are patentable regardless of the discussion on page 7 of the office action, third full paragraph. Applicants are not under a duty to discuss that paragraph, but reserve the right to discuss it if such a duty later arises. Please remove this rejection.

Regarding claim 34, claim 34 depends from claim 22 and, therefore, contains all the limitations of claim 22. As discussed above, the 900-patent fails to teach or suggest the elements of claim 22. Thus, the 900-patent also fails to teach or suggest the elements of claim 34. Because claim 34 is patentable regardless of the discussion on page 7 of the office action, fourth full paragraph. Applicants are not under a duty to discuss that paragraph, but Applicants reserve the right to discuss it if such a duty later arises. Please remove this rejection.

Claim 24 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Tseng. As discussed above, Tseng does not teach spraying a composition comprising a solvent onto a medical device, which claim 24 requires. Therefore, claim 24 is patentable regardless of the discussion in section 12 of the office action. Applicants are not under a

duty to discuss that section, but Applicants reserve the right to discuss it if such a duty later arises. Please remove this rejection.

Claim 8-10, 15-18, and 20 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Fan in view of Zhong. As discussed above, Fan does not make claim 5 obvious. Zhong does not supply the elements present in claim 5, but missing from Fan. Thus, this combination does not make claim 5 obvious. The claims referenced in section 13 of the office action depend from claim 5 and are, therefore, patentable regardless of the discussion in this section. Applicants are not under a duty to discuss this section, but Applicants reserve the right to discuss it if such a duty later arises.

Regarding claims 9-10, claims 9-10 depend from claim 5 and, therefore, contain all the limitations of claim 5. As discussed above, the cited art fails to teach or suggest the elements of claim 5. Thus, any reasons referred to on page 8 of the office action, third full paragraph, fails to establish prima facie obviousness of claims 9 or 10. And these claims are patentable regardless of the discussion on page 8 of the office action, third full paragraph. Applicants are not under a duty to discuss that paragraph, but Applicants reserve the right to discuss it if such a duty later arises. Please remove this rejection.

Regarding claims 15-16, claims 15-16 depend from claim 5 and, therefore, contain all the limitations of claim 5. As discussed above, the cited art fails to teach or suggest the elements of claim 5. Thus, any reasons referred to on page 8 of the office action, fourth full paragraph, fail to establish prima facie obviousness of claims 9 or 10. And these claims are patentable regardless of the discussion on page 8 of the office action, third full paragraph. Applicants are not under a duty to discuss that paragraph, but Applicants reserve the right to discuss it if such a duty later arises. Please remove this rejection.

Regarding claims 17-18, claims 17-18 depend from claim 5 and, therefore, contain all the limitations of claim 5. As discussed above, the cited art fails to teach or suggest the elements of claim 5. Thus, any reasons referred to on page 8 of the office action, fourth full paragraph, fail to establish prima facie obviousness of claims 9 or 10.

And these claims are patentable regardless of the discussion on page 8 of the office action, third full paragraph. Applicants are not under a duty to discuss that paragraph, but Applicants reserve the right to discuss it if such a duty later arises. Please remove this rejection.

Moreover, once again the examiner takes notice of what one of ordinary skill in the art would know. M.P.E.P. § 2144.03 states that “the rationale for supporting an obviousness rejection may be based on common knowledge in the art or ‘well-known’ prior art” and the “examiner may take official notice of facts outside of the record which are *capable of instant and unquestionable demonstration* as being ‘well-known’ in the art.” If an applicant traverses such an assertion, the examiner is required to cite a reference in support of her position. Applicants traverse that assertion and ask for such a reference.

Regarding claim 20, claim 20 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Fan in view of Zhong. Claim 20 depends from claim 5 and, therefore, contains all the limitations of claim 5. As discussed above, the cited art fails to teach or suggest the elements of claim 5. Thus, any reasons referred to on page 10 of the office action, third full paragraph, fail to establish prima facie obviousness of claim 20. And this claim is patentable regardless of the discussion. Applicants are not under a duty to discuss that paragraph, but Applicants reserve the right to discuss it if such a duty later arises. Please remove this rejection.

Without depicting a stent in its expanded form and its unexpanded form, a prior art reference cannot visually portray a partially expanded stent. The art does not contain such a depiction, which leaves a verbal disclosure as a possibility. Please point out where in the disclosure of Fan combined with Zhong the combination verbally discloses a partially expanded stent.

Claims 21, 30, and 31 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Fan in view of Tseng.

Regarding claims 21, 30, and 31, claims 21, 30, and 31 depend from claim 5 and, therefore, contain all the limitations of claim 5. As discussed above, the cited art fails to teach or suggest the elements of claim 5. Thus, any reasons referred to in section 14 of the office action fail to establish prima facie obviousness of claims 9 or 10. And these claims are patentable regardless of the discussion in section 14 of the office action, Applicants are not under a duty to discuss that section, but Applicants reserve the right to discuss it if such a duty later arises. Please remove this rejection.

Claims 20 and 32 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Fan in view of Whitbourne.

Regarding claims 20 and 32, claims 20 and 32 depend from claim 5 and, therefore, contain all the limitations of claim 5. As discussed above, the cited art fails to teach or suggest the elements of claim 5. Thus, any reasons referred to in section 15 of the office action fail to establish prima facie obviousness of claims 9 or 10. And these claims are patentable regardless of the discussion in section 15 of the office action, Applicants are not under a duty to discuss that section, but Applicants reserve the right to discuss it if such a duty later arises. Please remove this rejection.

Claim 25 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Tseng in view of Whitbourne.

Regarding claim 25, claim 25 depends from claim 1 and, therefore, contains all the limitations of claim 1. As discussed above, Tseng fails to teach or suggest all the elements of claim 1. Thus, any reasons referred to in section 16 of the office action fail to make claim 25 obvious. And these claims are patentable regardless of the discussion in section 16 of the office action, and Applicants are not under a duty to discuss that section, but Applicants reserve the right to discuss it if such a duty later arises. Please remove this rejection.

Claims 1, 2, 4, 24, and 35 are rejected under 35 U.S.C. §103(a) as being unpatentable over Berg, U.S. Patent No. 5,464,650, the 650-patent, in view of Pursley, U.S. Patent No. 6,030,371, the 371-patent.

The examiner states that Pursley teaches applying a polymer solution to a pre-heated metal mandrel substrate. With all due respect to the examiner, that statement is not true. Throughout the specification of the 371-patent, any polymer application involving heat is done with either a powdered polymer or an atomized molten polymer. (Abstract, lines 4 and 6; column 2, line 46; column 3, line 26; column 4, lines 2 and 4; column 6, lines 7, 26, 41, and 65; column 7, lines 1, 6, 7, 10, 15, 18, 53, 55, and 66; column 8, lines 1, 5, 9, 10, 11, and 15; column 9, lines 40, 42, and 47). A fluidized bed employs particulate polymer material.

Claims 3 and 33 of the 371-patent recites the method steps of claim 1 and add that the polymer materials are provided in solution. But the method of claim 1 does not recite or encompass a heating step. Claim 8 recites the first use of a heating step in terms that specify that claim 8 FURTHER comprises the step of heating and that the polymer material is in POWDER form.

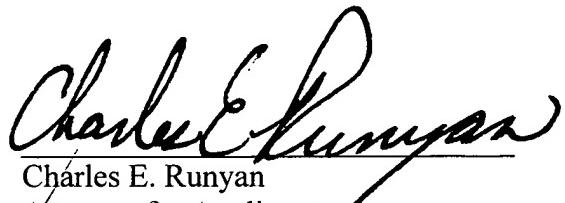
The 371-patent nowhere links heating a metal substrate with spraying a solvent-based polymer component. In fact, the disclosure goes to great lengths to show that when a metal substrate is heated, the polymer component should be provided as a solid polymer.

One of ordinary skill in the art would not learn to use a solvent-based polymer component with a heated substrate from the 371-patent. Therefore, the cited art combination does not in fact teach or suggest each and every element of claim 1, 2, 4, 24, and 35. Since the 371-patent does not teach driving off a solvent using a heated substrate, it would not have been obvious to one of ordinary skill in the art to apply the teaching of the 371-patent with the method of the 650-patent

Please remove this rejection under 35 U.S.C. § 103(a).

Since all claims are in a condition for allowance, please issue a Notice of Allowability so stating. If I can be of any help, please contact me.

Respectfully submitted,



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